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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/565,799

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Yasuhiro Kajihara

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EXAMINER

LAU, JONATHAN S

ART UNIT

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1623

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/565,799	Applicant(s) KAJIHARA ET AL.	
	Examiner Jonathan S. Lau	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 Apr 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) 1-3 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4 pgs / 06 Jul 2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application is the national stage entry of PCT/JP04/11036, filed 27 Jul 2004; and claims benefit of foreign priority document JAPAN 2003-202594, filed 28 Jul 2003; however, applicant has not filed a certified copy of the JAPAN 2003-202594 application as required by 35 U.S.C. 119(b). At present an English language translation of this foreign priority document is not of record.

Claims 1-8 are pending in the current application. Claims 1-3, drawn to non-elected inventions, are withdrawn. Claims 4-8 are examined on the merits herein.

Election/Restrictions

Applicant's election without traverse of the invention of Group II, claims 4-8, in the reply filed on 04 Apr 2008 is acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-3 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 04 Apr 2008.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in JAPAN on 28 Jul 2003. It is noted, however, that applicant has not

filed a certified copy of the JAPAN 2003-202594 application as required by 35 U.S.C. 119(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4-8 are drawn to the compound of claim 2, and claim 2 recites "An aminated complex-type oligosaccharide derivative of the formula (1)..." The language "derivative of" in claim 2 may be interpreted to mean "A derivative of an aminated complex-type oligosaccharide of the formula (1)..." or "An aminated complex-type oligosaccharide of the formula (1)..." Therefore the language of claim 2 is indefinite for failing to particularly point out and distinctly claim the compound which applicant regards as the invention. Claims 4-8 depend from claim 2 and incorporate all limitations therein, including the language that renders the claim indefinite.

Thus, one of ordinary skill in the art could not interpret the metes and bounds of the patent protection desired as to " derivative ". Therefore, the scope of claim is indefinite as to the claims encompassed thereby.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4, 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rademacher et al. (US Patent 5,280,113, issued 18 Jan 1994, cited in PTO-892) in view of Wong et al. (Biochem J., 1994, 300, p843-850, provided by Applicant in IDS filed 06 Jul 2006).

Rademacher discloses glycoconjugates formed by the process of bonding to an N-haloacetylated glycosamine (column 5, lines 5-17). Rademacher discloses the process of forming a glycopeptide by conjugating the compound Gal β 1-4GlcNAc β 1-2Man α 1-6(Gal β 1-4GlcNAc β 1-2Man α 1-3)-Man β 1-4GlcNAc β 1-4GlcNAc (column 22, lines 55-65). Rademacher discloses the haloacetylated glycosylamines reacted with a

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thiol R'SH to form a thioether (spanning column 12, lines 35-65 and column 13, lines 1-10). The haloacetylation of the glycosamine of compound Gal β 1-4GlcNAc β 1-2Man α 1-6(Gal β 1-4GlcNAc β 1-2Man α 1-3)-Man β 1-4GlcNAc β 1-4GlcNAc gives the compound of instant claim 2 in which R¹ is –NH-(CO)-(CH₂)₁-CH₂X and R² and R³ are the formula (3) as defined in instant claim 2. Rademacher discloses the release of oligosaccharides from glycoproteins by chemical or enzymatic methods (column 1, lines 55-56).

Rademacher does not specifically disclose the formation of a glycopeptide by bonding said N-haloacetylated glycosamine to the thiol group of an amino acid (instant claims 4 and 5). Rademacher does not specifically disclose the process for preparing a glycopeptide characterized by cleaving a saccharide of a glycopeptide from an amino acid and subsequently bonding an aminated complex-type oligosaccharide derivative to the resulting peptide (instant claim 7).

Wong teaches the glycosylation of proteins using N-glycosyl haloacetamides site specific to a cysteine (abstract), or the thiol group of an amino acid. Wong teaches the method of conjugating a defined oligosaccharide to cysteine side chains on a protein provides a finer-tuned strategy for synthetic glycosylation of proteins, and suggests the replacement of natural N-linked glycosylation sites with synthetic cysteine-linked ones (page 849, left column, 2nd paragraph in Discussion section). Wong teaches this method allows one to obtain glycoproteins with homogeneous carbohydrate structures attached (page 849, left column, 2nd paragraph in Discussion section). Wong teaches cysteine-linked oligosaccharides mimic the natural N-linkage and can be released from

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neoglycoproteins, whereas there is no scheme for the release of unprotected sugars from neoglycoproteins (page 849, left column, 4th paragraph in Discussion section).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the invention of Rademacher with the teaching of Wong. Both Rademacher and Wong are drawn to the field of conjugating N-glycosyl haloacetamides to proteins. One of ordinary skill in the art would be motivated to combine Rademacher with the teaching of Wong because Wong teaches conjugating a defined oligosaccharide to cysteine side chains on a protein provides a finer-tuned strategy for synthetic glycosylation of proteins. One of ordinary skill in the art would have a reasonable expectation of success in combining Rademacher with the teaching of Wong because Rademacher discloses the haloacetylated glycosylamines reacted with a thiol R'SH to form a thioether, and a cysteine side chain is a thiol R'SH. Rademacher discloses the release of oligosaccharides from glycoproteins by chemical or enzymatic methods. Wong teaches the replacement of sites of natural glycosylation with synthetic cysteine-linked ones.

It would have been obvious to one of ordinary skill in the art to cleave a saccharide of a glycopeptide from an amino acid and subsequently bond an aminated complex-type oligosaccharide to the resulting peptide. One would have been motivated to combine Rademacher in view of Wong to replace oligosaccharides from glycoproteins with said aminated complex-type oligosaccharide because Wong teaches this allows one to obtain glycoproteins with homogeneous carbohydrate structures

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attached and that cysteine-linked oligosaccharides mimic the natural N-linkage and can be released from neoglycoproteins.

Claims 4-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rademacher et al. (US Patent 5,280,113, issued 18 Jan 1994, cited in PTO-892) in view of Wong et al. (Biochem J., 1994, 300, p843-850, provided by Applicant in IDS filed 06 Jul 2006) and further in view of Wright et al. (Trends in Biotechnology, 1997, 15, p26-32, cited in PTO-892).

Rademacher in view of Wong renders obvious as above.

Rademacher in view of Wong does not specifically teach the peptide being an antibody.

Wright teaches all antibodies are glycosylated at conserved positions and the presence of carbohydrate can be critical (abstract). Wright teaches antibodies are glycosylated with a $\text{Gal}\beta 1-4\text{GlcNAc}\beta 1-2\text{Man}\alpha 1-6(\text{Gal}\beta 1-4\text{GlcNAc}\beta 1-2\text{Man}\alpha 1-3)\text{-Man}\beta 1-4\text{GlcNAc}\beta 1-4(\text{Fuc})\text{-GlcNAc}$ oligosaccharide (page 28, figure 2 at top of page, structure 4).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Rademacher in view of Wong with the teaching of Wright of the peptide being an antibody. Rademacher, Wong and Wright are all drawn to the field of glycosylation of peptides. One of skill in the art would be motivated to combine Rademacher in view of Wong with the teaching of Wright because Wright teaches all antibodies are glycosylated at conserved positions and the presence of carbohydrate

can be critical. One of ordinary skill in the art would have reasonable expectation of success in combining Rademacher in view of Wong with the teaching of Wright because Wright teaches antibodies are glycosylated with an oligosaccharide $\text{Gal}\beta 1-4\text{GlcNAc}\beta 1-2\text{Man}\alpha 1-6(\text{Gal}\beta 1-4\text{GlcNAc}\beta 1-2\text{Man}\alpha 1-3)-\text{Man}\beta 1-4\text{GlcNAc}\beta 1-4(\text{Fuc})-\text{GlcNAc}$ which is similar in structure to the oligosaccharide taught by Rademacher $\text{Gal}\beta 1-4\text{GlcNAc}\beta 1-2\text{Man}\alpha 1-6(\text{Gal}\beta 1-4\text{GlcNAc}\beta 1-2\text{Man}\alpha 1-3)-\text{Man}\beta 1-4\text{GlcNAc}\beta 1-4\text{GlcNAc}$.

Conclusion

No claim is found to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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